

store after shipment in interstate commerce, the defendants caused a number of tablets to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged tablets being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drug failed to bear a label containing an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged drug contained phenobarbital, a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the drug failed to bear a label containing the name, and quantity or the proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the repackaged drug was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of the active ingredient, phenobarbital, and the name, and quantity or proportion of the ingredient, hyoscyamine; and, Section 502 (f) (1), the labeling of the repackaged drug failed to bear adequate directions for use.

DISPOSITION: June 18, 1952. The corporation and Defendants Nelligan and Brown having entered pleas of guilty to count 1 of the information and Defendant Brawley having entered a plea of guilty to count 2 of the information, the court imposed a fine of \$750 against the corporation, \$250 against Defendant Nelligan, \$100 against Defendant Brown, and \$100 against Defendant Brawley.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3804. Adulteration and misbranding of allylisopropyl barbiturate sodium capsules and Hemotene tablets. U. S. v. Midwest Chemical Development Corp. Plea of nolo contendere. Fine, \$400. (F. D. C. No. 31581. Sample Nos. 10142-L, 16763-L.)

INFORMATION FILED: February 7, 1952, Northern District of Ohio, against the Midwest Chemical Development Corp., from Cleveland, Ohio.

ALLEGED SHIPMENT: On or about March 2, 1951, from the State of Ohio into the States of Michigan and California.

LABEL, IN PART: "Manufactured for: Diacin Chemical Co. * * * Detroit, Michigan * * * Each capsule contains: Allyl Isopropyl Barbiturate Sodium 1½ gr." and "270 Tablets Hemotene With Organic Iron and B-12 Distributed by Halco Corp. Los Angeles, Calif. Six Hemotene Tablets provide: * * * Vitamin C 120 milligrams Vitamin D 2000 U. S. P. Units."

NATURE OF CHARGE: *Allylisopropyl barbiturate sodium capsules.* Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since it contained less than 1½ grains of allylisopropyl barbiturate sodium per capsule as represented. Misbranding, Section 502 (a), the label declaration "Each capsule contains: Allyl Isopropyl Barbiturate Sodium 1½ gr." was false and misleading.

Hemotene tablets. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since 6 tablets of the article were represented to supply 120 mg. of vitamin C and 2,000 U. S. P. units of vitamin D, whereas 6 tablets would supply lesser

amounts of such vitamins. Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading since the statements represented and suggested that 6 tablets of the article would supply 120 mg. of vitamin C and 2,000 U. S. P. units of vitamin D, and would supply four times the minimum daily requirements for vitamin C and five times the minimum daily requirements for vitamin D, whereas the article would supply smaller amounts of vitamin C and vitamin D than was represented and smaller proportions of the minimum daily requirements for vitamin C and vitamin D than was represented.

The information alleged also that another article, known as vitamin A and D tablets, was adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: June 27, 1952. A plea of nolo contendere having been entered, the court imposed a fine of \$400.

3805. Adulteration of sulfadiazine tablets. U. S. v. 19 Bottles * * * .
(F. D. C. No. 33276. Sample No. 6556-L.)

LIBEL FILED: May 26, 1952, District of Massachusetts.

ALLEGED SHIPMENT: On or about May 5, 1952, by the Robin Pharmacal Corp., from Brooklyn, N. Y.

PRODUCT: 19 1,000-tablet bottles of *sulfadiazine tablets* at Boston, Mass.

LABEL, IN PART: (Bottle) "1000 Sulfadiazine * * * (2-Sulfanilamido-pyrimidine) Compressed Tablets (Scored) 0.5 Gm. (7.7 Grains)."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Sulfadiazine Tablets," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the official standard since the standard provides that sulfadiazine tablets contain not less than 95 percent of the labeled amount of sulfadiazine, whereas the article contained less than that amount, namely, not more than 77 percent of the labeled amount of sulfadiazine.

DISPOSITION: August 18, 1952. The Robin Pharmacal Corp., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the drug be released under bond for reprocessing to bring it into compliance with the law, under the supervision of the Federal Security Agency.

3806. Adulteration of sodium salicylate and iodide with colchicine. U. S. v. 10 Cartons, etc. (F. D. C. No. 33338. Sample Nos. 7723-L, 7724-L.)

LIBEL FILED: July 9, 1952, Western District of New York.

ALLEGED SHIPMENT: On or about May 16, 1952, by the Addison Laboratories, from Philadelphia, Pa.

PRODUCT: 20 cartons, each containing 50 ampuls, of *sodium salicylate and iodide with colchicine* at Buffalo, N. Y. Examination showed that some of the ampuls contained less than the declared amounts of the sodium salicylate and sodium iodide ingredients, and that some of the ampuls (15.5 grain strength) contained the drug aminophylline instead of the declared ingredients.

LABEL, IN PART: (Ampul) "Size: 20 cc. * * * Sodium Salicylate and Iodide with Colchicine Each 20 cc. contain a sterile solution of: Sodium Iodide 15.5 gr. Sodium Salicylate 15.5 gr. Colchicine 0.65 mg." and "Size: 20 cc. * * * Sodium Salicylate and Iodide with